

110TH CONGRESS
1ST SESSION

S. 1834

To improve the health of Americans through the gradual elimination of tobacco products.

IN THE SENATE OF THE UNITED STATES

JULY 19, 2007

Mr. ENZI introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To improve the health of Americans through the gradual elimination of tobacco products.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Help End Addiction to Lethal Tobacco Habits Act” or
6 the “HEALTH Act”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—REQUIREMENTS ON MANUFACTURERS

Sec. 101. Reports.

Sec. 102. Tobacco testing.
 Sec. 103. Warning labels.

TITLE II—TOBACCO USE SURVEYS

Sec. 201. Tobacco use survey.

TITLE III—REDUCTION IN UNITED STATES TOBACCO USERS

Sec. 301. Amendment to the Public Health Service Act.

TITLE IV—REVENUE PROVISIONS

Sec. 401. Increase in excise tax rate on tobacco products based on relative health risk.

TITLE V—CESSATION AND PREVENTION

Sec. 501. Food and Drug Administration Tobacco Risk Classification Panel.
 Sec. 502. Authority to prohibit nicotine.
 Sec. 503. Counter-advertising.
 Sec. 504. Medicare coverage of counseling for cessation of tobacco use.
 Sec. 505. Medicare coverage of tobacco cessation pharmacotherapy.
 Sec. 506. Tobacco cessation for Federal employee health benefits plans.
 Sec. 507. Matching grants for States that use a significant portion of master settlement agreement funds for tobacco control and cessation.

1 **TITLE I—REQUIREMENTS ON** 2 **MANUFACTURERS**

3 **SEC. 101. REPORTS.**

4 (a) **FEDERAL CIGARETTE LABELING.**—Section 7(a)
 5 of the Federal Cigarette Labeling and Advertising Act (15
 6 U.S.C. 1335a(a)) is amended by striking “which does not
 7 identify the company which uses the ingredients or the
 8 brand of cigarettes which contain the ingredients” and in-
 9 serting “and a specification of the quantity of nicotine and
 10 tar contained in each such product”.

11 (b) **SMOKELESS TOBACCO.**—Section 7(a) of the Com-
 12 prehensive Smokeless Tobacco Health Education Act of
 13 1986 (15 U.S.C. 4403(a)(1)) is amended—

1 (1) in subparagraph (A), by striking “which
 2 does not identify the company which uses the ingre-
 3 dients or the brand of smokeless tobacco which con-
 4 tains the ingredients”; and

5 (2) in subparagraph (B), by inserting “and tar”
 6 after “nicotine”.

7 **SEC. 102. TOBACCO TESTING.**

8 (a) **FEDERAL CIGARETTE LABELING AND ADVER-**
 9 **TISING ACT.**—Section 7 of the Federal Cigarette Labeling
 10 and Advertising Act (15 U.S.C. 1335a) is amended by
 11 adding at the end the following:

12 “(c) **TOBACCO TESTING.**—

13 “(1) **STANDARDS AND PRACTICES FOR MEAS-**
 14 **URING AND ANALYZING TOBACCO CONSTITUENTS.**—

15 “(A) **IN GENERAL.**—Not later than 18
 16 months after the date of enactment of the Help
 17 End Addiction to Lethal Tobacco Habits Act,
 18 the Secretary of Commerce, acting through the
 19 Director of the National Institute of Standards
 20 and Technology and in consultation with the
 21 Secretary of Health and Human Services, shall
 22 develop and publish in the Federal Register
 23 standards and best practices for—

24 “(i) the sampling of tobacco and to-
 25 bacco products for testing; and

1 “(ii) accurate measurement and anal-
2 ysis of tobacco constituents, including—

3 “(I) nicotine;

4 “(II) tar;

5 “(III) carbon monoxide; and

6 “(IV) any other constituent as
7 may be necessary.

8 “(B) COMPONENTS.—The standards and
9 best practices developed under subparagraph
10 (A) shall address the need for—

11 “(i) standardized measurement and
12 verification practices for tobacco con-
13 stituent reports made by all persons under
14 this section, taking into account—

15 “(I) protocols and standards cur-
16 rently in use by persons making such
17 reports;

18 “(II) existing protocols and
19 standards developed by members of
20 the public health community;

21 “(III) the report required under
22 subsection (b)(1)(B); and

23 “(IV) such other factors as the
24 Secretary of Commerce and the Sec-

1 retary of Health and Human Services
2 determine to be appropriate;

3 “(ii) measurement and verification of
4 actions taken to reduce the harm or expo-
5 sure from tobacco products; and

6 “(iii) such other measurement and
7 verification standards as the Secretary of
8 Commerce and the Secretary of Health
9 and Human Services determine to be ap-
10 propriate.

11 “(C) OPTIONS.—The standards and best
12 practices developed under subparagraph (A)
13 may require the measurement of the content,
14 rather than the yield of tobacco ingredients,
15 components, or additives.

16 “(2) APPLICABLE LAW.—To ensure that high
17 quality information is produced, the standards and
18 best practices developed under paragraph (1) shall
19 conform to the guidelines established under section
20 515 of the Treasury and General Government Ap-
21 propriations Act, 2001 (commonly known as the
22 Data Quality Act) (44 U.S.C. 3516 note; 114 Stat.
23 2763A–1543), as enacted into law by section 1(a)(3)
24 of Public Law 106–554.

1 “(3) TRANSITIONAL MEASUREMENT STAND-
 2 ARDS.—Until such time as the standards and best
 3 practices developed under paragraph (1) are avail-
 4 able, persons reporting to Federal Trade Commis-
 5 sion under this section shall use—

6 “(A) the conditions described in the Inter-
 7 national Organization for Standardization
 8 standard ISO 3308;

9 “(B) the International Organization for
 10 Standardization standards 4387 to determine
 11 tar, 10315 to determine nicotine, and 8454 to
 12 determine carbon monoxide; and

13 “(C) the sampling specified in the Inter-
 14 national Organization for Standardization
 15 standard ISO 8243.”.

16 (b) COMPREHENSIVE SMOKELESS TOBACCO HEALTH
 17 EDUCATION ACT OF 1986.—Section 4 of the Comprehen-
 18 sive Smokeless Tobacco Health Education Act of 1986 (15
 19 U.S.C. 4403) is amended by adding at the end the fol-
 20 lowing:

21 “(c) TOBACCO TESTING.—

22 “(1) STANDARDS AND PRACTICES FOR MEAS-
 23 URING AND ANALYZING SMOKELESS TOBACCO CON-
 24 STITUENTS.—

1 “(A) IN GENERAL.—Not later than 18
2 months after the date of enactment of the Help
3 End Addiction to Lethal Tobacco Habits Act,
4 the Secretary of Commerce, acting through the
5 Director of the National Institute of Standards
6 and Technology and in consultation with the
7 Secretary of Health and Human Services, shall
8 develop and publish in the Federal Register
9 standards and best practices for—

10 “(i) the sampling of smokeless tobacco
11 and tobacco products for testing; and

12 “(ii) accurate measurement and anal-
13 ysis of smokeless tobacco constituents, in-
14 cluding—

15 “(I) nicotine;

16 “(II) tar;

17 “(III) nitrosamines; and

18 “(IV) any other constituent as
19 may be necessary.

20 “(B) COMPONENTS.—The standards and
21 best practices developed under subparagraph
22 (A) shall address the need for—

23 “(i) standardized measurement and
24 verification practices for tobacco con-

1 stituent reports made by all persons under
2 this section, taking into account—

3 “(I) protocols and standards cur-
4 rently in use by persons making such
5 reports;

6 “(II) existing protocols and
7 standards developed by members of
8 the public health community;

9 “(III) the report required under
10 subsection (b)(1)(B); and

11 “(IV) such other factors as the
12 Secretary of Commerce and the Sec-
13 retary of Health and Human Services
14 determine to be appropriate;

15 “(ii) measurement and verification of
16 actions taken to reduce the harm or expo-
17 sure from smokeless tobacco products; and

18 “(iii) such other measurement and
19 verification standards as the Secretary of
20 Commerce and the Secretary of Health
21 and Human Services determine to be ap-
22 propriate.

23 “(C) OPTIONS.—The standards and best
24 practices developed under subparagraph (A)
25 may require the measurement of the content,

1 rather than the yield of tobacco ingredients,
2 components, or additives.

3 “(2) APPLICABLE LAW.—To ensure that high
4 quality information is produced, the standards and
5 best practices developed under paragraph (1) shall
6 conform to the guidelines established under section
7 515 of the Treasury and General Government Ap-
8 propriations Act, 2001 (commonly known as the
9 Data Quality Act) (44 U.S.C. 3516 note; 114 Stat.
10 2763A–1543), as enacted into law by section 1(a)(3)
11 of Public Law 106–554.

12 “(3) TRANSITIONAL MEASUREMENT STAND-
13 ARDS.—Until such time as the standards and best
14 practices developed under paragraph (1) are avail-
15 able, persons reporting to Federal Trade Commis-
16 sion under this section shall use—

17 “(A) the International Organization for
18 Standardization standards 15592–3 to deter-
19 mine tar and 15152 to determine nicotine; and

20 “(B) the sampling specified in the Inter-
21 national Organization for Standardization
22 standard ISO 4874.”.

23 **SEC. 103. WARNING LABELS.**

24 (a) CIGARETTE LABELING AND ADVERTISING WARN-
25 INGS.—

1 (1) IN GENERAL.—Section 4(a) of the Federal
2 Cigarette Labeling and Advertising Act (15 U.S.C.
3 1333(a)) is amended—

4 (A) in paragraph (1) by striking “section,
5 one of the following labels:” and all that fol-
6 lows, and inserting the following:

7 “section—

8 “(A) 1 of the following labels:

9 “SURGEON GENERAL’S WARNING: Smok-
10 ing kills.

11 “SURGEON GENERAL’S WARNING: Smok-
12 ing seriously harms you and others around you.

13 “SURGEON GENERAL’S WARNING: Smok-
14 ers die younger.

15 “SURGEON GENERAL’S WARNING: Smok-
16 ing clogs the arteries and causes heart attacks and
17 strokes.

18 “SURGEON GENERAL’S WARNING: Ciga-
19 rettes cause fatal lung cancer.

20 “SURGEON GENERAL’S WARNING: Smok-
21 ing when pregnant harms your baby.

22 “SURGEON GENERAL’S WARNING: Pro-
23 tect children: don’t make them breathe your smoke.

24 “SURGEON GENERAL’S WARNING: Smok-
25 ing is highly addictive, don’t start.

1 “SURGEON GENERAL’S WARNING: Stop-
2 ping smoking reduces the risk of fatal heart and
3 lung diseases.

4 “SURGEON GENERAL’S WARNING: Smok-
5 ing can cause a slow and painful death.

6 “SURGEON GENERAL’S WARNING: Get
7 help now to stop smoking: (telephone/postal address/
8 Internet address/consult your doctor/pharmacist).

9 “SURGEON GENERAL’S WARNING: Smok-
10 ing may reduce the blood flow and causes impotence.

11 “SURGEON GENERAL’S WARNING: Smok-
12 ing causes aging of the skin.

13 “SURGEON GENERAL’S WARNING: Smok-
14 ing can damage the sperm and decreases fertility.

15 “SURGEON GENERAL’S WARNING: Smoke
16 contains the toxic chemicals benzene, nitrosamines,
17 formaldehyde, and hydrogen cyanide.

18 “SURGEON GENERAL’S WARNING: Ciga-
19 rettes are addictive; and

20 “(B) a label on 1 side of the package indicating the
21 tar, nicotine, and carbon monoxide yields of the cigarettes
22 so that at least 10 percent of the corresponding surface
23 is covered, such label to be accompanied by the following
24 statements: ‘Nicotine is addictive.’, and ‘Tar and Carbon
25 Monoxide are harmful; there is no safe level.’.”;

1 (B) in paragraph (2) by striking “section,
2 one of the following labels:” and all that fol-
3 lows, and inserting the following:

4 “section—

5 “(A) 1 of the following labels:

6 “SURGEON GENERAL’S WARNING: Smok-
7 ing kills.

8 “SURGEON GENERAL’S WARNING: Smok-
9 ing seriously harms you and others around you.

10 “SURGEON GENERAL’S WARNING: Smok-
11 ers die younger.

12 “SURGEON GENERAL’S WARNING: Smok-
13 ing clogs the arteries and causes heart attacks and
14 strokes.

15 “SURGEON GENERAL’S WARNING: Ciga-
16 rettes cause fatal lung cancer.

17 “SURGEON GENERAL’S WARNING: Smok-
18 ing when pregnant harms your baby.

19 “SURGEON GENERAL’S WARNING: Pro-
20 tect children: don’t make them breathe your smoke.

21 “SURGEON GENERAL’S WARNING: Smok-
22 ing is highly addictive, don’t start.

23 “SURGEON GENERAL’S WARNING: Stop-
24 ping smoking reduces the risk of fatal heart and
25 lung diseases.

1 “SURGEON GENERAL’S WARNING: Smok-
2 ing can cause a slow and painful death.

3 “SURGEON GENERAL’S WARNING: Get
4 help now to stop smoking: (telephone/postal address/
5 Internet address/consult your doctor/pharmacist).

6 “SURGEON GENERAL’S WARNING: Smok-
7 ing may reduce the blood flow and causes impotence.

8 “SURGEON GENERAL’S WARNING: Smok-
9 ing causes aging of the skin.

10 “SURGEON GENERAL’S WARNING: Smok-
11 ing can damage the sperm and decreases fertility.

12 “SURGEON GENERAL’S WARNING: Smoke
13 contains the toxic chemicals benzene, nitrosamines,
14 formaldehyde, and hydrogen cyanide.

15 “SURGEON GENERAL’S WARNING: Ciga-
16 rettes are addictive; and

17 “(B) a label on the advertisement indicating the tar,
18 nicotine, and carbon monoxide yields of the cigarettes so
19 that at least 10 percent of the surface is covered, such
20 label to be accompanied by the following statements: ‘Nie-
21 otine is addictive.’, and ‘Tar and Carbon Monoxide are
22 harmful; there is no safe level.’”; and

23 (C) in paragraph (3) by striking “section,
24 one of the following labels:” and all that fol-
25 lows, and inserting the following:

1 “section—

2 “(A) 1 of the following labels:

3 “SURGEON GENERAL’S WARNING: Smok-
4 ing kills.

5 “SURGEON GENERAL’S WARNING: Smok-
6 ing seriously harms you and others around you.

7 “SURGEON GENERAL’S WARNING: Smok-
8 ers die younger.

9 “SURGEON GENERAL’S WARNING: Smok-
10 ing clogs the arteries and causes heart attacks and
11 strokes.

12 “SURGEON GENERAL’S WARNING: Ciga-
13 rettes cause fatal lung cancer.

14 “SURGEON GENERAL’S WARNING: Smok-
15 ing when pregnant harms your baby.

16 “SURGEON GENERAL’S WARNING: Pro-
17 tect children: don’t make them breathe your smoke.

18 “SURGEON GENERAL’S WARNING: Smok-
19 ing is highly addictive, don’t start.

20 “SURGEON GENERAL’S WARNING: Stop-
21 ping smoking reduces the risk of fatal heart and
22 lung diseases.

23 “SURGEON GENERAL’S WARNING: Smok-
24 ing can cause a slow and painful death.

1 “SURGEON GENERAL’S WARNING: Get
2 help now to stop smoking: (telephone/postal address/
3 Internet address/consult your doctor/pharmacist).

4 “SURGEON GENERAL’S WARNING: Smok-
5 ing may reduce the blood flow and causes impotence.

6 “SURGEON GENERAL’S WARNING: Smok-
7 ing causes aging of the skin.

8 “SURGEON GENERAL’S WARNING: Smok-
9 ing can damage the sperm and decreases fertility.

10 “SURGEON GENERAL’S WARNING: Smoke
11 contains the toxic chemicals benzene, nitrosamines,
12 formaldehyde, and hydrogen cyanide.

13 “SURGEON GENERAL’S WARNING: Ciga-
14 rettes are addictive; and

15 “(B) a label on the advertisement indicating the tar,
16 nicotine, and carbon monoxide yields of the cigarettes so
17 that at least 10 percent of the surface is covered, such
18 label to be accompanied by the following statements: ‘Nic-
19 otine is addictive.’, and ‘Tar and Carbon Monoxide are
20 harmful; there is no safe level.’.”.

21 (2) LOCATION AND GRAPHICS.—Section 4(b) of
22 the Federal Cigarette Labeling and Advertising Act
23 (15 U.S.C. 1333(b)) is amended—

24 (A) in paragraph (1), by striking “shall be
25 located in the place label statements were” and

1 all that follows through the end and inserting
2 “shall:

3 “(A) Occupy at least 50 percent of the front
4 and rear panels of the package on which it is dis-
5 played and printed directly on the package under-
6 neath the cellophane or other clear wrapping. All
7 text of the warning described in such paragraph (1)
8 shall be in conspicuous and legible 17-point type, un-
9 less the text of the label statement would occupy
10 more than 70 percent of such area, in which case
11 the text may be in a smaller conspicuous and legible
12 type size. The text shall be black on a white back-
13 ground, or white on a black background, in a man-
14 ner that contrasts, by typography, layout, or color,
15 with all other printed material on the package.

16 “(B) Be accompanied by color graphics depict-
17 ing the negative health consequences of smoking.”;

18 (B) in paragraph (2), by adding at the end
19 the following: “Each label statement shall be
20 accompanied by color graphics depicting the
21 negative health consequences of smoking.”; and

22 (C) in paragraph (3), by adding at the end
23 the following: “Each label statement shall be
24 accompanied by color graphics depicting the
25 negative health consequences of smoking.”.

1 (3) LABEL ROTATION.—Section 4(c)(1) of the
 2 Federal Cigarette Labeling and Advertising Act (15
 3 U.S.C. 1333(c)(1)) is amended—

4 (A) by striking “quarterly”; and

5 (B) by inserting before the period at the
 6 end “in equal distribution and display.”.

7 (b) SMOKELESS TOBACCO LABELS AND ADVER-
 8 TISING WARNINGS.—Section 3(a)(1) of the Comprehen-
 9 sive Smokeless Tobacco Health Education Act of 1986 (15
 10 U.S.C. 4402(a)(1)) is amended—

11 (1) in subsection (a)(1), by striking “Act, one
 12 of the following labels:” and all that follows, and in-
 13 serting the following:

14 “Act—

15 “(A) 1 of the following labels:

16 “WARNING: Smokeless tobacco is addictive.

17 “WARNING: This product causes mouth dis-
 18 eases.

19 “WARNING: Use of this product can cause
 20 cancer.

21 “WARNING: This tobacco product can damage
 22 your health and is addictive.

23 “WARNING: This product contains cancer-
 24 causing agents.

25 “WARNING: Tobacco can kill.

1 “WARNING: Tobacco users die younger.

2 “WARNING: Tobacco use when pregnant
3 harms your baby.

4 “WARNING: Tobacco is highly addictive, don’t
5 start.

6 “WARNING: Get help now to stop using to-
7 bacco: (telephone/postal address/Internet address/
8 consult your doctor/pharmacist).

9 “WARNING: Tobacco contains the toxic chemi-
10 cals benzene, nitrosamines, formaldehyde, and hy-
11 drogen cyanide; and

12 “(B) a label on 1 side of the package indicating the
13 tar, nicotine, and nitrosamines yields of the products so
14 that at least 10 percent of the corresponding surface is
15 covered, such label to be accompanied by the following
16 statements: ‘Nicotine is addictive.’, and ‘Tar and
17 Nitrosamines are harmful; there is no safe level.’.”;

18 (2) by striking subsection (b) and inserting the
19 following:

20 “(b) LABEL FORMAT.—Each label statement re-
21 quired by paragraph (1) shall:

22 “(1) Be located on the 2 principal display pan-
23 els of the package, but not the bottom, and each
24 label statement shall comprise at least 40 percent of
25 such panels of the package. All of the text of the

1 warning described in paragraph (1) shall appear in
 2 17 point conspicuous and legible type in a manner
 3 that contrasts by typography, layout, or color, with
 4 all other printed material on the package. The text
 5 of the label statement shall be black on a white
 6 background, or white on a black background, in an
 7 alternating fashion under the plan submitted under
 8 subsection (d), except that if the text of a label
 9 statement would occupy more than 70 percent of the
 10 area specified by subparagraph (A), such text may
 11 appear in a smaller type size.”; and

12 (3) in subsection (c)(2)—

13 (A) by striking “every 4 months”; and

14 (B) by inserting before the period at the
 15 end “in equal distribution and display”.

16 **TITLE II—TOBACCO USE** 17 **SURVEYS**

18 **SEC. 201. TOBACCO USE SURVEY.**

19 (a) ANNUAL SURVEY.—Not later than January 1,
 20 2008, and annually thereafter, the Secretary shall conduct
 21 a survey to support the calculation of allowances under
 22 title XXX of the Public Health Service Act (as added by
 23 section 301). Such survey shall—

24 (1) determine—

1 (A) the percentage of all individuals who
2 used a tobacco product within the 30-day period
3 prior to the conduct of the survey; and

4 (B) the percentage of individuals identified
5 under paragraph (1) who identify each brand of
6 each type of tobacco product as the usual brand
7 smoked or used within such 30-day period;

8 (2) be conducted in coordination with existing
9 survey activities;

10 (3) be based on a nationally representative sam-
11 ple of at least 200,000 completed interviews of indi-
12 viduals;

13 (4) be a household-based in person survey; and

14 (5) contain any other elements as may be nec-
15 essary.

16 (b) EXISTING DATA SOURCES.—The Secretary may
17 combine, replace or otherwise alter the following existing
18 surveys to collect needed data in the most efficient and
19 cost-effective manner:

20 (1) The National Health Interview Survey.

21 (2) The National Survey on Drug Use and
22 Health under section 505 of the Public Health Serv-
23 ice Act (42 U.S.C. 290aa–4).

24 (3) The Behavior Risk Factor Surveillance Sur-
25 vey.

1 (4) The Monitoring the Future study.

2 (5) The Youth Risk Behavior Surveillance Sys-
3 tem.

4 (6) The current Population Survey Tobacco
5 Use Supplement.

6 **TITLE III—REDUCTION IN**
7 **UNITED STATES TOBACCO**
8 **USERS**

9 **SEC. 301. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
10 **ACT.**

11 The Public Health Service Act (42 U.S.C. 201 et
12 seq.) is amended by adding at the end the following:

13 **“TITLE XXX—REDUCTION IN**
14 **UNITED STATES TOBACCO**
15 **USERS**

16 **“SEC. 3001. PURPOSE.**

17 “It is the purpose of this title to—

18 “(1) reduce the adverse health effects of to-
19 bacco use through reductions in the annual size of
20 the tobacco market from 2006 levels in the United
21 States;

22 “(2) effectuate such reductions by requiring
23 compliance by tobacco manufacturers with pre-
24 scribed user limitations by specified deadlines, which
25 limitations may be met through alternative methods

1 of compliance provided by a market share allocation
 2 and transfer system; and

3 “(3) encourage tobacco control and prevention,
 4 and smoking cessation.

5 **“SEC. 3002. DEFINITIONS.**

6 “In this title:

7 “(1) ACTUAL 2006 TOBACCO USERS.—The term
 8 ‘actual 2006 tobacco users’ for affected brands
 9 means the total number of United States tobacco
 10 users in calendar year 2006 as determined using
 11 data reported in surveys under title II of the Help
 12 End Addiction to Lethal Tobacco Habits Act.

13 “(2) AFFECTED BRAND.—The term ‘affected
 14 brand’ means a brand marketed by an affected man-
 15 ufacturer that is subject to tobacco user reduction
 16 requirements or limitations under this title.

17 “(3) AFFECTED MANUFACTURER.—The term
 18 ‘affected manufacturer’ means a manufacturer of to-
 19 bacco products (as defined in section 5702 of the In-
 20 ternal Revenue Code of 1986) who applies for a per-
 21 mit under section 40.62 of title 26, Code of Federal
 22 Regulations (or successor regulations).

23 “(4) ALLOWABLE 2006 TOBACCO USERS.—The
 24 term ‘allowable 2006 tobacco users’ means a feder-

1 ally enforceable limitation on the number of United
2 States tobacco users applicable to the brand.

3 “(5) ALLOWANCE.—The term ‘allowance’
4 means an authorization, allocated to an affected
5 brand by the Secretary under this title, to sell to,
6 during or after a specified calendar year, 1 United
7 States tobacco user.

8 “(6) BASELINE.—The term ‘baseline’ means
9 the number of United States tobacco users of an af-
10 fected brand, calculated as follows:

11 “(A) For each affected brand that was in
12 commercial operation as of January 1, 2007,
13 the baseline shall be the annual average number
14 of United States tobacco users of the brand
15 during calendar years 2004, 2005, and 2006,
16 as determined using data recorded by the De-
17 partment of Health and Human Services pursu-
18 ant to surveys under the following:

19 “(i) The National Health Interview
20 Survey.

21 “(ii) The National Survey on Drug
22 Use and Health under section 505 of the
23 Public Health Service Act (42 U.S.C.
24 290aa-4).

1 “(iii) The Behavior Risk Factor Sur-
2 veillance Survey.

3 “(iv) The Monitoring the Future
4 study.

5 “(v) The Youth Risk Behavior Sur-
6 veillance System.

7 “(vi) The current Population Survey
8 Tobacco Use Supplement.

9 “(B) For any affected brand for which
10 such survey data was not collected, the baseline
11 shall be the annual average number of tobacco
12 users for those years, as calculated pursuant to
13 a method which the Secretary shall prescribe by
14 regulation not later than 9 months after the
15 date of enactment of this title.

16 “(C) The Secretary may, upon application
17 or on his or her own motion, supplement data
18 needed in support of this title and correct any
19 factual errors in data from which baselines have
20 been calculated. Corrected data shall be used
21 for purposes of issuing allowances under the
22 title. Such corrections shall not be subject to ju-
23 dicial review, nor shall the failure of the Sec-
24 retary to correct an alleged factual error in
25 such reports be subject to judicial review.

1 “(7) BRAND.—The term ‘brand’ has the mean-
2 ing given such term in section 5702 of the Internal
3 Revenue Code of 1986.

4 “(8) COMPLIANCE PLAN.—The term ‘compli-
5 ance plan’ means a schedule and description of the
6 method or methods for compliance and certification
7 by the owner or operator that the manufacturer is
8 in compliance with the requirements of this title.

9 “(9) DESIGNATED REPRESENTATIVE.—The
10 term ‘designated representative’ means a responsible
11 person or official authorized by the owner or oper-
12 ator of an affected brand to represent the owner or
13 operator in matters pertaining to the holding, trans-
14 fer, or disposition of allowances allocated to an af-
15 fected brand, and the submission of and compliance
16 with permits, permit applications, and compliance
17 plans for the affected brand.

18 “(10) EXISTING BRAND.—The term ‘existing
19 brand’ means a brand of tobacco product that com-
20 menced commercial distribution before the date of
21 enactment of this title.

22 “(11) NEW BRAND.—The term ‘new brand’
23 means a brand of tobacco product that commences
24 commercial distribution on or after the date of en-
25 actment of this title.

1 “(12) PERMITTING AUTHORITY.—The term
2 ‘permitting authority’ means the Alcohol and To-
3 bacco Tax and Trade Bureau.

4 “(13) UNITED STATES TOBACCO USER.—The
5 term ‘United States tobacco user’ means a person in
6 the United States who uses a tobacco product (as
7 defined in section 5702 of the Internal Revenue
8 Code of 1986) as determined using surveys de-
9 scribed in title II of the Help End Addiction to Le-
10 thal Tobacco Habits Act.

11 **“SEC. 3003. UNITED STATES TOBACCO USER ALLOWANCE**
12 **PROGRAM FOR EXISTING AND NEW BRANDS.**

13 “(a) ALLOCATIONS OF ANNUAL ALLOWANCES FOR
14 EXISTING AND NEW BRANDS.—

15 “(1) IN GENERAL.—For the United States to-
16 bacco user limitation programs under this title, the
17 Secretary shall allocate annual allowances for the af-
18 fected brand, to be held or distributed by the des-
19 ignated representative of the owner or operator of
20 each affected brand of an affected manufacturer in
21 accordance with this title, in an amount that is
22 equal to the annual United States tobacco user limi-
23 tation calculated under this section and sections
24 3004, 3005, or 3007, except as otherwise specifically
25 provided elsewhere in this title.

1 “(2) LIMITATION.—

2 “(A) IN GENERAL.—Except as provided in
3 section 3007, beginning on January 1, 2015,
4 the Secretary shall not allocate annual allow-
5 ances pursuant to section 3005 in such an
6 amount as would result in total annual allow-
7 ances in excess of 30,000,000. For purposes of
8 the preceding sentence, the Secretary shall not
9 take into account unused allowances carried
10 forward by owners and operators of affected
11 brands or by other persons holding such allow-
12 ances, following the year for which they were al-
13 located.

14 “(B) PRO RATA REDUCTIONS.—If deter-
15 mined necessary to comply with the limitation
16 imposed under subparagraph (A), the Secretary
17 shall reduce, on a pro rata basis, the Phase II
18 allowance allocations for each affected brand,
19 subject to the requirements of section 3005.

20 “(3) ANNUAL ALLOCATION.—The Secretary
21 shall allocate allowances for each affected brand of
22 an affected manufacturer annually, as provided for
23 in this section, section 3004, and section 3005.

24 “(4) REMOVAL OF BRANDS.—Except as pro-
25 vided for in section 3007, the removal of an existing

1 affected brand or manufacturer from commercial op-
2 eration at any time after the date of the enactment
3 of this title shall not terminate or otherwise affect
4 the allocation of allowances pursuant to section 3004
5 or 3005 to which the brand is entitled. Allowances
6 shall be allocated by the Secretary without cost to
7 the recipient.

8 “(5) ELECTION.—Any person who may make
9 an election concerning the amount of allowances to
10 be allocated to a brand or brands shall make such
11 election and so inform the Secretary not later than
12 March 31, 2015, in the case of an election under
13 section 3005. If such person fails to make such elec-
14 tion, the Secretary shall set forth for each brand
15 owned or operated by such person, the amount of al-
16 lowances reflecting the election that would, in the
17 judgment of the Secretary, provide the greatest ben-
18 efit for the owner or operator of the brand.

19 “(b) ALLOWANCE TRANSFER SYSTEM.—

20 “(1) IN GENERAL.—Allowances allocated under
21 this title may be transferred among the designated
22 representatives of the owners or operators of af-
23 fected manufacturers under this title and any other
24 person who holds such allowances, as provided for by

1 the allowance system regulations promulgated under
2 paragraph (2).

3 “(2) REGULATIONS.—Not later than 18 months
4 after the date of enactment of this title, the Sec-
5 retary shall promulgate regulations for purposes of
6 paragraph (1). Such regulations shall—

7 “(A) provide for the establishment of the
8 allowance system described in this section, in-
9 cluding requirements for the allocation, trans-
10 fer, and use of allowances under this title;

11 “(B) prohibit the use of any allowance
12 prior to the calendar year for which the allow-
13 ance was allocated; and

14 “(C) provide, consistent with the purposes
15 of this title, for the identification of unused al-
16 lowances, and for such unused allowances to be
17 carried forward and added to allowances allo-
18 cated in subsequent years, including allowances
19 allocated to brands subject to Phase I require-
20 ments (as described in section 3004) which are
21 applied to limitation requirements in Phase II
22 (as described in section 3005); and

23 “(D) establish a system for issuing, record-
24 ing, and tracking allowances under this section,
25 such regulations to specify all necessary proce-

dures and requirements for an orderly and competitive functioning of the allowance system, and all allowance allocations and transfers shall, upon recordation by the Secretary, be deemed a part of each brand's permit requirements pursuant to section 3006, without any further permit review and revision.

“(3) CERTIFICATION.—Transfers of allowances under this subsection shall not be effective until written certification of the transfer, signed by a responsible official of each party to the transfer, is received and recorded by the Secretary within 30 days.

“(4) PREALLOCATION TRANSFERS.—Regulations under this subsection shall permit the transfer of allowances prior to the issuance of such allowances under subsection (a). Recorded preallocation transfers shall be deducted by the Secretary from the number of allowances which would otherwise be allocated to the transferor, and added to those allowances allocated to the transferee. Preallocation transfers shall not affect the prohibition contained in this subsection against the use of allowances prior to the year for which they are allocated.

“(c) NEW AFFECTED BRANDS.—

1 “(1) IN GENERAL.—After January 1, 2009, it
 2 shall be unlawful for a new affected brand to sell to
 3 a number of United States tobacco users in excess
 4 of the number of allowances held for the brand by
 5 the brand’s owner or operator. Such new affected
 6 brands shall not be eligible for an allocation of
 7 United States tobacco user allowances under this
 8 section. New affected brands may obtain allowances
 9 from any person, in accordance with this section.

10 “(2) ENFORCEMENT.—The owner or operator
 11 of any new affected brand in violation of this sub-
 12 section shall be liable for fulfilling the obligations
 13 specified in section 3008.

14 “(d) NATURE OF ALLOWANCES.—

15 “(1) IN GENERAL.—An allowance allocated
 16 under this title shall be a limited authorization to
 17 sell to 1 United States tobacco user in accordance
 18 with the provisions of this title. Such allowance shall
 19 not constitute a property right. Allowances under
 20 this title, once allocated to a person by the Sec-
 21 retary, may be received, held, and temporarily or
 22 permanently transferred in accordance with this title
 23 (and the regulations promulgated hereunder) with-
 24 out regard to whether or not a permit is in effect
 25 under the permitting authority with respect to the

1 brand for which such allowance was originally allo-
 2 cated and recorded.

3 “(2) RULES OF CONSTRUCTION.—Nothing in
 4 this title or in any other provision of law shall be
 5 construed to limit the authority of the United States
 6 to terminate or limit an authorization under this
 7 title. Nothing in this section relating to allowances
 8 shall be construed as affecting the application of, or
 9 compliance with, any other provision of this title to
 10 an affected brand or manufacturer. Nothing in this
 11 section shall be construed as requiring a change of
 12 any kind in any State law regulating excise tax rates
 13 or affecting any State law regarding such State reg-
 14 ulation or as limiting State regulation under such a
 15 State law.

16 “(e) PROHIBITIONS.—

17 “(1) IN GENERAL.—It shall be unlawful—

18 “(A) for any person to hold, use, or trans-
 19 fer any allowance allocated under this title, ex-
 20 cept in accordance with regulations promul-
 21 gated by the Secretary;

22 “(B) for any affected brand to sell to
 23 United States tobacco users in excess of the
 24 number of allowances held for that brand for

1 that year by the owner or operator of the
2 brand.

3 “(2) EFFECT OF PROVISION.—Upon the alloca-
4 tion of allowances under this title, the prohibition
5 contained in paragraph (1)(B) shall supersede any
6 other United States tobacco user limitation applica-
7 ble under this title to the brands for which such al-
8 lowances are allocated.

9 “(3) LIMITATION.—An allowance under this
10 title may not be used prior to the calendar year for
11 which such allowance is allocated.

12 “(4) RULE OF CONSTRUCTION.—Nothing in
13 this section, or in the allowance system regulations
14 promulgated under this section, shall be construed to
15 relieve the Secretary of the Treasury of permitting,
16 monitoring, and enforcement obligations under this
17 title of under the Internal Revenue Code of 1986,
18 nor relieve affected manufacturers of their require-
19 ments and liabilities under this title or such Code.

20 “(f) APPLICABILITY OF THE ANTITRUST LAWS.—

21 “(1) IN GENERAL.—Nothing in this section
22 shall be construed to effect—

23 “(A) the applicability of the antitrust laws
24 to the transfer, use, or sale of allowances; or

1 “(B) the authority of the Federal Trade
 2 Commission under any provision of law relating
 3 to unfair methods of competition or anti-
 4 competitive acts or practices.

5 “(2) DEFINITION.—As used in this section, the
 6 term ‘antitrust laws’ means those Acts set forth in
 7 section 1 of the Clayton Act (15 U.S.C. 12).

8 **“SEC. 3004. PHASE I TOBACCO USER REQUIREMENTS.**

9 “(a) UNITED STATES TOBACCO USER LIMITA-
 10 TIONS.—

11 “(1) IN GENERAL.—Not later than 9 months
 12 after the date of enactment of this title, the Sec-
 13 retary shall publish in the Federal Register a list of
 14 affected brands and their allowances for the years
 15 2009 through 2015. Such allowances for each such
 16 brand for 2009 shall equal the product of—

17 “(A) the average of—

18 “(i) the baseline of the brand in-
 19 volved, divided by the total number of
 20 United States tobacco users as determined
 21 using survey data under section 201 of the
 22 Help End Addiction to Lethal Tobacco
 23 Habits Act; and

24 “(ii) the production of that brand pro-
 25 duced in that year for the domestic market

1 (as determined by the Secretary of Agri-
 2 culture), divided by the total production
 3 for the domestic market for that year (as
 4 determined by the Secretary of Agri-
 5 culture); and

6 “(B) the total number of United States to-
 7 bacco users (as determined using survey data
 8 under section 201 of the Help End Addiction to
 9 Lethal Tobacco Habits Act).

10 “(2) PROHIBITION.—After January 1, 2009, it
 11 shall be unlawful for any affected brand to sell to
 12 United States tobacco users in excess of the limita-
 13 tion determined under paragraph (1) for such brand
 14 (stated as a total number of allowances in such list
 15 for phase I), unless—

16 “(A) the user limitations applicable to such
 17 brand have been achieved pursuant to this sec-
 18 tion and section 3005; or

19 “(B) the owner or operator of such brand
 20 holds allowances to sell to not less than the
 21 brand’s total annual users;
 22 except that, after January 1, 2015, the user limita-
 23 tions established in this section shall be superseded
 24 by those established under section 3005. The owner
 25 or operator of any brand in violation of this section

1 shall be fully liable for such violation including liabil-
 2 ity for fulfilling the obligations specified in section
 3 3008.

4 “(b) SUBSTITUTIONS.—The owner or operator of an
 5 affected brand under subsection (a) may include in its sec-
 6 tion 3006 permit application and proposed compliance
 7 plan, a proposal to reassign, in whole or in part, the af-
 8 fected brand’s tobacco user reduction requirements to any
 9 other brand or brands under the control of such owner
 10 or operator. Such proposal shall specify—

11 “(1) the designation of the substitute brand or
 12 brands to which any part of the reduction obliga-
 13 tions of subsection (a) shall be required, in addition
 14 to, or in lieu of, any original affected brands des-
 15 ignated under such subsection;

16 “(2) the original affected brand’s baseline, the
 17 actual and allowable 2006 tobacco users, and the au-
 18 thorized annual allowance allocation stated in the
 19 list in subsection (a)(1);

20 “(3) the calculation of the annual average
 21 United States tobacco users for calendar years 2004,
 22 2005, and 2006, sold to by the substitute brand or
 23 brands, based on the baseline for each brand;

1 “(4) the user limitations that would be applica-
 2 ble to the original and substitute affected brands
 3 under the substitution proposal;

4 “(5) documentation, to the satisfaction of the
 5 Secretary, that the reassigned user limitations will,
 6 in total, achieve the same or greater user reduction
 7 than would have been achieved by the original af-
 8 fected brand and the substitute brand or brands
 9 without such substitution; and

10 “(6) such other information as the Secretary
 11 may require.

12 “(c) SECRETARY’S ACTION ON SUBSTITUTION PRO-
 13 POSALS.—

14 “(1) FINAL ACTION.—

15 “(A) IN GENERAL.—The Secretary shall
 16 take final action on a substitution proposal
 17 under subsection (b) in accordance with section
 18 3006 if the substitution proposal complies with
 19 the requirements of this subsection.

20 “(B) APPROVAL.—The Secretary may ap-
 21 prove a substitution proposal under subsection
 22 (b) in whole or in part and with such modifica-
 23 tions or conditions as may be consistent with
 24 the orderly functioning of the allowance system

1 under this title and which will ensure the user
2 reductions contemplated by this title.

3 “(C) DISAPPROVAL.—If a substitution pro-
4 posal does not meet the requirements of sub-
5 section (b), the Secretary shall disapprove it.

6 “(D) LIMITATION.—The owner or operator
7 of a brand on the list in subsection (a) shall not
8 substitute another brand or brands without the
9 prior approval of the Secretary.

10 “(2) ACTIONS UPON APPROVAL.—

11 “(A) IN GENERAL.—Upon the approval of
12 a substitution proposal under this subsection,
13 each substitute brand, and each manufacturer
14 with such brand, shall be deemed to be affected
15 under this title, and the Secretary of the Treas-
16 ury shall revise any permits to the original and
17 substitute affected manufacturer and brand in
18 accordance with the approved substitution plan
19 and section 3006.

20 “(B) REVISED ALLOCATION.—The Sec-
21 retary shall allocate allowances for the original
22 and substitute affected brands in accordance
23 with the approved substitution proposal pursu-
24 ant to section 3003.

1 “(C) LIMITATION.—It shall be unlawful for
2 any manufacturer or brand that is allocated al-
3 lowances pursuant to this section to sell to
4 United States tobacco users in excess of the
5 limitation provided for in the approved substi-
6 tution plan unless the owner or operator of each
7 brand governed by the permit and approved
8 substitution plan holds allowances to sell to not
9 less than the brand’s total annual users. The
10 owner or operator of any original or substitute
11 affected brand operated in violation of this sub-
12 section shall be fully liable for such violation,
13 including liability for fulfilling the obligations
14 specified in section 3008.

15 “(3) DISAPPROVAL.—If a substitution proposal
16 is disapproved, the Secretary shall allocate allow-
17 ances to the original affected brand or brands in ac-
18 cordance with subsection (a).

19 “(4) RULE OF CONSTRUCTION.—Nothing in
20 this subsection shall be construed as an event of
21 force majeure or a commercial impracticability or in
22 any other way as a basis for excused nonperform-
23 ance by a manufacturer.

1 **“SEC. 3005. PHASE II TOBACCO USER REQUIREMENTS.**

2 “(a) APPLICABILITY.—Beginning on January 1,
3 2015, each existing affected brand shall be subject to the
4 limitations or requirements of this section.

5 “(b) AFFECTED BRANDS AND MANUFACTURERS.—

6 “(1) AFFECTED BRANDS.—Each brand that is
7 subject to an annual tobacco user limitation under
8 this section shall be deemed to be an affected brand
9 under this title.

10 “(2) AFFECTED MANUFACTURERS.—Each man-
11 ufacturer that includes one or more affected brands
12 is an affected manufacturer.

13 “(3) BRANDS NOT IN OPERATION IN 2008.—In
14 the case of a brand that was not in operation during
15 calendar year 2008, the United States tobacco users
16 for a calendar year after 2008, as determined by the
17 Secretary, shall be used in lieu of the 2008 rate.

18 “(4) PUBLICATION OF LIST.—

19 “(A) PROPOSED LIST.—Not later than De-
20 cember 31, 2013, the Secretary shall publish a
21 proposed list of the annual Phase II allowance
22 allocations for the years 2016 through 2027.

23 “(B) FINAL LIST.—After notice and op-
24 portunity for public comment, but not later
25 than November 30, 2014, the Secretary shall
26 publish a final list of the annual Phase II allo-

1 cations, subject to the provisions of section
2 3005.

3 “(c) LIABILITY.—The owner or operator of any
4 brand operated in violation of this section shall be liable
5 under this Act for fulfilling the obligations specified in sec-
6 tion 3008.

7 “(d) UNLAWFUL ACTS.—It shall be unlawful for a
8 brand—

9 “(1) beginning on January 1, 2015, to exceed
10 an annual United States tobacco user limitation
11 equal to the product of the brand’s baseline multi-
12 plied by $\frac{2}{3}$, unless the owner or operator of such
13 brand holds allowances to sell to not less than the
14 brand’s total annual users; and

15 “(2) beginning on January 1, 2027, to exceed
16 an annual United States tobacco user limitation
17 equal to the product of its baseline multiplied by 0.1,
18 unless the owner or operator holds allowances to sell
19 to not less than the brand’s total annual United
20 States tobacco users.

21 **“SEC. 3006. PERMITS AND COMPLIANCE PLANS.**

22 “(a) PERMIT PROGRAM.—The provisions of this title
23 shall be implemented, subject to section 3003, through the
24 modification of, or an addition to, a permit issued to a
25 brand that is subject to this title and issued and enforced

1 in accordance with the provisions of section 5713 of the
 2 Internal Revenue Code of 1986. Any such permit issued
 3 by the Secretary of the Treasury shall prohibit—

4 “(1) annual sales to United States tobacco
 5 users in excess of the number of allowances the
 6 owner or operator, or the designated representative
 7 of the owners or operators, of the brand hold for the
 8 brand under this title;

9 “(2) the brand from exceeding applicable
 10 United States tobacco user levels;

11 “(3) the use of any allowance prior to the year
 12 for which it was allocated; and

13 “(4) noncompliance with any other provision of
 14 the permit.

15 No permit shall be issued under this section that is incon-
 16 sistent with the requirements of this title, and section
 17 5713 of the Internal Revenue Code of 1986, as applicable.

18 “(b) COMPLIANCE PLAN.—

19 “(1) IN GENERAL.—An application for a permit
 20 under this section shall contain a compliance plan
 21 with respect to compliance by the manufacturer with
 22 the requirements of this title. The Secretary may re-
 23 quire that the owner or operator of 2 or more af-
 24 fected manufacturers submit an integrated compli-

1 ance plan providing an overall plan for achieving
2 compliance by the affected manufacturers.

3 “(2) COVERAGE OF ALL BRANDS.—Where an
4 affected manufacturer consists of more than 1 af-
5 fected brand, the compliance plan shall cover all
6 such brands.

7 “(3) STATEMENT THAT BRAND WILL MEET RE-
8 QUIREMENTS.—Except as provided under section
9 3004(c)(1)(B), the submission of a statement by the
10 owner or operator, or the designated representative
11 of the owner or operator, of a brand that is subject
12 to the limitation requirements of sections 3004 and
13 3005, that the brand will meet the applicable limita-
14 tion requirements of such sections in a timely man-
15 ner and that the owners and operators will hold al-
16 lowances to sell to not less than the total annual
17 United States tobacco users of the brand, shall be
18 deemed to meet the proposed and approved compli-
19 ance planning requirements of this section and sec-
20 tion 5713 of the Internal Revenue Code of 1986.

21 “(4) AUTOMATIC AMENDING OF PERMITS AND
22 PLANS.—The recording by the Secretary of a trans-
23 fer of allowances under this title shall be deemed to
24 automatically amend all applicable proposed or ap-

proved permit applications, compliance plans, and permits under this section.

“(5) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as affecting allowances under this title.

“(c) REGULATIONS; ISSUANCE OF PERMITS.—

“(1) REGULATIONS.—Not later than 9 months after the date of the enactment of this title, the Secretary of the Treasury shall promulgate regulations, in consultation with the Secretary of Health and Human Services, in accordance with sections 5712 and 5713 of the Internal Revenue Code of 1986, to modify the permit program for affected manufacturers under this title.

“(2) ISSUANCE OF PERMITS.—

“(A) IN GENERAL.—Following the promulgation of regulations under paragraph (1), the Secretary of the Treasury shall issue modified permits to implement the requirements of sections 3004 and 3005 and the allowances provided for under section 3003 to the owner or operator of each affected manufacturer under sections 3004 and 3005. The permit issued in accordance with this subsection for an affected manufacturer shall provide that the affected

1 brands of the affected manufacturer may not
 2 sell to an annual number of United States to-
 3 bacco users that is in excess of the number of
 4 allowances the owner or operator or designated
 5 representative hold for the brand.

6 “(B) FIRST PHASE PERMITS.—

7 “(i) IN GENERAL.—The Secretary of
 8 the Treasury shall issue permits to af-
 9 fected manufacturers under section 5713
 10 of the Internal Revenue Code of 1986.

11 “(ii) PERMIT APPLICATION AND COM-
 12 PLIANCE PLAN.—

13 “(I) IN GENERAL.—Not later
 14 than 12 months after the date of the
 15 enactment of this title, the designated
 16 representative of the owner or oper-
 17 ator, or the owner and operator, of
 18 each affected manufacturer shall sub-
 19 mit a permit application and compli-
 20 ance plan for that manufacturer in
 21 accordance with regulations promul-
 22 gated and issued by the Secretary of
 23 the Treasury under clause (i). The
 24 permit application and the compliance
 25 plan shall be binding on the owner or

1 operator or the designated representa-
2 tive of owners and operators for pur-
3 poses of this title, and shall be en-
4 forceable in lieu of a permit until a
5 permit is issued by the Secretary of
6 the Treasury for the manufacturer.

7 “(II) ACTION ON COMPLIANCE
8 PLANS.—The Secretary shall review
9 each proposed compliance plan to de-
10 termine whether it satisfies the re-
11 quirements of this title, and shall
12 communicate such review to the Sec-
13 retary of the Treasury, who shall ap-
14 prove or disapprove such plan within
15 6 months after the receipt of a com-
16 plete submission. If a plan is dis-
17 approved, it may be resubmitted for
18 approval with such changes as the
19 Secretary of the Treasury shall re-
20 quire consistent with the requirements
21 of this title and within such period as
22 the Secretary prescribes as part of
23 such disapproval.

24 “(C) SECOND PHASE PERMITS.—

1 “(i) IN GENERAL.—The Secretary of
2 the Treasury shall issue permits to af-
3 fected manufacturers under section 5713
4 of the Internal Revenue Code of 1986.

5 “(ii) PERMIT APPLICATION AND COM-
6 PLIANCE PLAN.—Annually beginning in
7 January 1, 2014, the designated represent-
8 ative of the owner or operator, or the
9 owner and operator, of each affected man-
10 ufacturer shall submit a permit application
11 and compliance plan for that manufacturer
12 in accordance with regulations issued by
13 the Secretary of the Treasury under clause
14 (i). The permit application and the compli-
15 ance plan shall be binding on the owner or
16 operator or the designated representative
17 of owners and operators for purposes of
18 this title, and shall be enforceable in lieu
19 of a permit until a permit is issued by the
20 Secretary of the Treasury for the manufac-
21 turer.

22 “(D) NEW BRANDS.—The owner or oper-
23 ator of each manufacturer that includes a new
24 brand shall submit a permit application and
25 compliance plan to the Secretary of the Treas-

1 ury not later than the date on which the brand
 2 commences operation. The Secretary of the
 3 Treasury shall issue a permit to the owner or
 4 operator of the brand, or the designated rep-
 5 resentative thereof, if the brand satisfies the re-
 6 quirements of sections 5712 and 5713 of the
 7 Internal Revenue Code of 1986 and this title.

8 “(d) AMENDMENT OF PERMIT APPLICATION AND
 9 COMPLIANCE PLAN.—At any time after the submission of
 10 a permit application and compliance plan under this sec-
 11 tion, the applicant may submit a revised application and
 12 compliance plan, in accordance with the requirements of
 13 this section and the Internal Revenue Code of 1986.

14 “(e) PROHIBITION.—It shall be unlawful—

15 “(1) for an owner or operator, or designated
 16 representative, required to submit a permit applica-
 17 tion or compliance plan under this title to fail to
 18 submit such application or plan in accordance with
 19 the regulations promulgated under this section or to
 20 otherwise fail to comply with regulations imple-
 21 menting this section; and

22 “(2) for any person to operate any manufac-
 23 turer subject to this title except in compliance with
 24 the terms and requirements of a permit application

1 and compliance plan (including amendments thereto)
 2 or permit issued by the Secretary of the Treasury.
 3 For purposes of this subsection, compliance with a permit
 4 issued under section 5713 of the Internal Revenue Code
 5 of 1986 which complies with this title for manufacturers
 6 subject to this title shall be deemed to be in compliance
 7 with this subsection.

8 “(f) CERTIFICATE OF REPRESENTATION AND MUL-
 9 TIPLE OWNERS.—

10 “(1) CERTIFICATE.—No permit shall be issued
 11 under this section to an affected brand until the des-
 12 ignated representative of the owners or operators
 13 has filed a certificate of representation with regard
 14 to matters under this title, including the holding and
 15 distribution of allowances and the proceeds of trans-
 16 actions involving allowances. Except as otherwise
 17 provided for in this subsection, where all legal or eq-
 18 uitable title to or interest in an affected brand is
 19 held by a single person, the certification shall state
 20 that all allowances received by the brand are deemed
 21 to be held for that person.

22 “(2) MULTIPLE OWNERS.—If there are multiple
 23 holders of a legal or equitable title to, or a leasehold
 24 interest in, such a brand, the certificate under para-
 25 graph (1) shall state—

1 “(A) that allowances and the proceeds of
 2 transactions involving allowances will be deemed
 3 to be held or distributed in proportion to each
 4 holder’s legal, equitable, leasehold, or contrac-
 5 tual reservation or entitlement; or

6 “(B) if such multiple holders have ex-
 7 pressly provided for a different distribution of
 8 allowances by contract, that allowances and the
 9 proceeds of transactions involving allowances
 10 will be deemed to be held or distributed in ac-
 11 cordance with the contract.

12 “(3) LEASEHOLDER AGREEMENTS.—A passive
 13 lessor, or a person who has an equitable interest
 14 through such lessor, whose rental payments are not
 15 based, either directly or indirectly, upon the reve-
 16 nues or income from the affected brand shall not be
 17 deemed to be a holder of a legal, equitable, lease-
 18 hold, or contractual interest for the purpose of hold-
 19 ing or distributing allowances as provided in this
 20 subsection, during either the term of such leasehold
 21 or thereafter, unless expressly provided for in the
 22 leasehold agreement.

23 **“SEC. 3007. EXCESS USERS PENALTY.**

24 “(a) EXCESS USERS PENALTY.—

1 “(1) IN GENERAL.—The owner or operator of
2 any brand or manufacturer subject to the require-
3 ments of section 3003, 3004 or 3005, that sells to
4 United States tobacco users for any calendar year
5 an amount in excess of the brand’s user limitation
6 requirement or of the allowances the owner or oper-
7 ator holds for use for the brand for that calendar
8 year shall be liable for the payment of an excess
9 users penalty.

10 “(2) DETERMINATION OF PENALTY.—The pen-
11 alty under paragraph (1) shall be an amount that
12 equals the product of—

13 “(A) the number of users in excess of the
14 brand’s user limitation requirement or of the al-
15 lowances the operator holds for use for the
16 brand for that year, as applicable; and

17 “(B) \$3,500.

18 “(3) PAYMENT.—A penalty under this sub-
19 section shall be due and payable without demand to
20 the Secretary of the Treasury. Any such payment
21 shall be deposited in the United States Treasury
22 pursuant to the Miscellaneous Receipts Act. Any
23 penalty due and payable under this section shall not
24 diminish the liability of the brand’s owner or oper-
25 ator for any fine, penalty, or assessment against the

1 brand for the same violation under any other section
2 of this title.

3 “(4) REGULATIONS.—Not later than 12 months
4 after the date of enactment of this title, the Sec-
5 retary shall promulgate regulations with respect to
6 the payment of penalties under this subsection.

7 “(b) EXCESS USERS OFFSET.—

8 “(1) IN GENERAL.—The owner or operator of
9 any affected manufacturer that sells to United
10 States tobacco users during any calendar year in ex-
11 cess of the brand’s limitation requirement or of the
12 allowances held for the brand for the calendar year,
13 shall be liable to offset the excess users by an equal
14 amount in the following calendar year, or such
15 longer period as the Secretary of the Treasury may
16 prescribe.

17 “(2) PLAN.—Not later than 60 days after the
18 end of the year in which the excess users occurred,
19 the owner or operator of the manufacturer shall sub-
20 mit to the Secretary a proposed plan to achieve the
21 offsets required under paragraph (1). Upon approval
22 of the proposed plan by the Secretary, as submitted,
23 modified, or conditioned, the plan shall be deemed to
24 be a condition of the operating permit under section

1 3006 for the brand without further review or review
2 of the permit.

3 “(3) DEDUCTION OF ALLOWANCES.—The Secretary
4 shall deduct allowances equal to the excess
5 from those allocated for the manufacturer for the
6 calendar year, or succeeding years during which offsets
7 are required under this section, following the
8 year in which the excess users occurred.

9 “(c) PENALTY ADJUSTMENT.—The Secretary of the
10 Treasury shall, by regulation, adjust the penalty amount
11 specified in subsection (a)(2)(B) to account for the excess
12 health costs per tobacco user and inflation, based on the
13 change in Medical Inflation (as reported annually by the
14 Council of Economic Advisors), on the date of enactment
15 and annually thereafter.

16 “(d) PROHIBITION.—It shall be unlawful for the
17 owner or operator of any manufacturer liable for a penalty
18 and offset under this section to fail—

19 “(1) to pay the penalty under subsection (a);

20 “(2) to provide, and thereafter comply with, a
21 compliance plan as required under subsection (b); or

22 “(3) to offset excess users as required under
23 subsection (b).

1 **“SEC. 3008. INVENTORIES; REPORTS; RECORDS.**

2 “(a) INVENTORIES.—Every manufacturer or im-
3 porter of tobacco products shall make a true and accurate
4 inventory at the time of commencing business, at the time
5 of concluding business, and at such other times, in such
6 manner and form, and to include such items, as the Sec-
7 retary of the Treasury shall by regulation prescribe. Such
8 inventories shall be subject to verification by any internal
9 revenue officer. The Secretary, in consultation with the
10 Secretary of the Treasury, shall develop and implement
11 processes to verify allowances issued under section 3003
12 against information in records of compliance.

13 “(b) REPORTS.—Every manufacturer or importer of
14 tobacco products shall make a report for each month and
15 for any portion of a month during which such manufac-
16 turer or importer engages in such business. Such report
17 shall be made regardless of whether any operations or
18 transactions occurred during the month or portion of a
19 month covered therein. The report for a month or portion
20 of a month in which business is commenced or is con-
21 cluded shall be conspicuously marked ‘Commencing Re-
22 port’ or ‘Concluding Report’, respectively. The original of
23 the report shall be submitted to the appropriate Alcohol
24 and Tobacco Tax and Trade Bureau officer not later than
25 the 20th day of the month succeeding the month covered

1 therein. Each report shall show, for the period covered,
2 the total quantity of tobacco products—

3 “(1) manufactured;

4 “(2) received in bond;

5 “(3) received by return to bond;

6 “(4) disclosed by inventory as an overage;

7 “(5) removed subject to tax;

8 “(6) removed in bond;

9 “(7) otherwise disposed of without determina-
10 tion of tax;

11 “(8) disclosed by inventory as a shortage; and

12 “(9) on hand, in bond, at the beginning of and
13 end of the month.

14 “(c) RECORDS.—Every affected manufacturer shall
15 keep records in accordance with section 40.183 of title 27,
16 Code of Federal Regulations (or successor regulations).
17 Affected manufacturers shall retain any issued permit,
18 compliance plan, if applicable, and any amendments there-
19 to, and documentation relating to allowances under section
20 3003 received, held and temporarily or permanently trans-
21 ferred, including certification of such transfer together
22 with the copy of the application and supporting docu-
23 ments.”.

TITLE IV—REVENUE PROVISIONS

SEC. 401. INCREASE IN EXCISE TAX RATE ON TOBACCO PRODUCTS BASED ON RELATIVE HEALTH RISK.

(a) CIGARETTES.—Section 5701(b) of the Internal Revenue Code of 1986 is amended—

(1) by striking “\$19.50 per thousand (\$17 per thousand on cigarettes removed during 2000 or 2001)” in paragraph (1) and inserting “\$19.50 plus the applicable risk amount per thousand”, and

(2) by striking “\$40.95 per thousand (\$35.70 per thousand on cigarettes removed during 2000 or 2001)” in paragraph (2) and inserting “\$40.95 plus the applicable risk amount per thousand”.

(b) CIGARS.—Section 5701(a) of the Internal Revenue Code of 1986 is amended—

(1) by striking “\$1.828 cents per thousand (\$1.594 cents per thousand on cigars removed during 2000 or 2001)” in paragraph (1) and inserting “\$1.828 cents plus the applicable risk amount per thousand”,

(2) by striking “20.719 percent (18.063 percent on cigars removed during 2000 or 2001)” in para-

1 graph (2) and inserting “20.719 percent plus the
2 applicable risk percentage”, and

3 (3) by striking “\$48.75 per thousand (\$42.50
4 per thousand on cigars removed during 2000 or
5 2001)” in paragraph (2) and inserting “\$48.75 plus
6 the applicable risk amount per thousand”.

7 (c) SMOKELESS TOBACCO.—Section 5701(e) of the
8 Internal Revenue Code of 1986 is amended—

9 (1) by striking “58.5 cents (51 cents on snuff
10 removed during 2000 or 2001)” in paragraph (1)
11 and inserting “58.5 cents plus the applicable risk
12 amount”, and

13 (2) by striking “19.5 cents (17 cents on chew-
14 ing tobacco removed during 2000 or 2001)” in para-
15 graph (2) and inserting “19.5 cents plus the applica-
16 ble risk amount”.

17 (d) APPLICABLE RISK AMOUNT.—Section 5701 of
18 the Internal Revenue Code of 1986 is amended by adding
19 at the end the following new subsection:

20 “(p) APPLICABLE RISK AMOUNT.—With respect to
21 each tobacco product or group of products classified by
22 the Tobacco Risk Classification Panel under the Food and
23 Drug Administration, the following applicable risk
24 amounts or percentages shall apply:

1 “(1) Small cigarettes: Class I—\$10; Class II—
2 \$20; and Class III—\$30.

3 “(2) Large cigarettes: Class I—\$20; Class II—
4 \$40; and Class III—\$60.

5 “(3) Small cigars: Class I—\$0.914; Class II—
6 \$1.828; and Class III—\$2.742.

7 “(4) Large cigars: Class I—5 percent; Class
8 II—10 percent; and Class III—15 percent, but not
9 more than \$73.12.

10 “(5) Smokeless (snuff): Class I—29.25 cents;
11 Class II—58.5 cents; and Class III—87.75 cents.

12 “(6) Smokeless (chewing): Class I—10 cents;
13 Class II—20 cents; and Class III—30 cents.”.

14 (e) FLOOR STOCKS TAXES.—

15 (1) IMPOSITION OF TAX.—On tobacco products
16 and cigarette papers and tubes manufactured in or
17 imported into the United States which are removed
18 before January 1, 2008, and held on such date for
19 sale by any person, there is hereby imposed a tax in
20 an amount equal to the excess of—

21 (A) the tax which would be imposed under
22 section 5701 of the Internal Revenue Code of
23 1986 on the article if the article had been re-
24 moved on such date, over

1 (B) the prior tax (if any) imposed under
2 section 5701 of such Code on such article.

3 (2) CREDIT AGAINST TAX.—Each person shall
4 be allowed as a credit against the taxes imposed by
5 paragraph (1) an amount equal to \$500. Such credit
6 shall not exceed the amount of taxes imposed by
7 paragraph (1) on January 1, 2008, for which such
8 person is liable.

9 (3) LIABILITY FOR TAX AND METHOD OF PAY-
10 MENT.—

11 (A) LIABILITY FOR TAX.—A person hold-
12 ing cigarettes on January 1, 2008, to which any
13 tax imposed by paragraph (1) applies shall be
14 liable for such tax.

15 (B) METHOD OF PAYMENT.—The tax im-
16 posed by paragraph (1) shall be paid in such
17 manner as the Secretary shall prescribe by reg-
18 ulations.

19 (C) TIME FOR PAYMENT.—The tax im-
20 posed by paragraph (1) shall be paid on or be-
21 fore April 1, 2008.

22 (4) ARTICLES IN FOREIGN TRADE ZONES.—
23 Notwithstanding the Act of June 18, 1934 (48 Stat.
24 998, 19 U.S.C. 81a) and any other provision of law,
25 any article which is located in a foreign trade zone

1 on January 1, 2004, shall be subject to the tax im-
2 posed by paragraph (1) if—

3 (A) internal revenue taxes have been deter-
4 mined, or customs duties liquidated, with re-
5 spect to such article before such date pursuant
6 to a request made under the 1st proviso of sec-
7 tion 3(a) of such Act, or

8 (B) such article is held on such date under
9 the supervision of a customs officer pursuant to
10 the 2d proviso of such section 3(a).

11 (5) DEFINITIONS.—For purposes of this sub-
12 section—

13 (A) IN GENERAL.—Terms used in this sub-
14 section which are also used in section 5702 of
15 the Internal Revenue Code of 1986 shall have
16 the respective meanings such terms have in
17 such section.

18 (B) SECRETARY.—The term “Secretary”
19 means the Secretary of the Treasury or the
20 Secretary’s delegate.

21 (6) CONTROLLED GROUPS.—Rules similar to
22 the rules of section 5061(e)(3) of such Code shall
23 apply for purposes of this subsection.

24 (7) OTHER LAWS APPLICABLE.—All provisions
25 of law, including penalties, applicable with respect to

1 the taxes imposed by section 5701 of such Code
2 shall, insofar as applicable and not inconsistent with
3 the provisions of this subsection, apply to the floor
4 stocks taxes imposed by paragraph (1), to the same
5 extent as if such taxes were imposed by such section
6 5701. The Secretary may treat any person who bore
7 the ultimate burden of the tax imposed by para-
8 graph (1) as the person to whom a credit or refund
9 under such provisions may be allowed or made.

10 (f) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to articles removed (as defined in
12 section 5702(k) of the Internal Revenue Code of 1986)
13 after December 31, 2007.

14 (g) USE OF AMOUNTS.—With respect to any increase
15 in revenues to the Treasury resulting from the provisions
16 of and amendments made by this section, without further
17 appropriation—

18 (1) 50 percent of such increase shall be trans-
19 ferred to the Federal Hospital Insurance Trust
20 Fund established under section 1817 of the Social
21 Security Act (42 U.S.C. 1395i),

22 (2) 25 percent of such increase shall be trans-
23 ferred to the States through the medicaid program
24 under title XIX of the Social Security Act (42
25 U.S.C. 1396 et seq.), and

(3) 25 percent of such increase shall be provided to the States through matching grants for the development and administration of programs to restrict youth access to tobacco products as provided for in regulations promulgated by the Secretary of Health and Human Services, including grants under section 3009 of the Public Health Service Act, and for counter-advertising under section 506C of the Public Health Service Act.

TITLE V—CESSATION AND PREVENTION

SEC. 501. FOOD AND DRUG ADMINISTRATION TOBACCO RISK CLASSIFICATION PANEL.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

“Subchapter I—Provisions Relating to Tobacco

“SEC. 765. TOBACCO RISK CLASSIFICATION PANEL.

“(a) TOBACCO PRODUCT CLASSES.—

“(1) IN GENERAL.—There are established the following classes of tobacco products:

“(A) CLASS I—GENERAL RISK.—A tobacco

product or group of products with typical health risks shall be referred to as a ‘Class I product’.

1 “(B) CLASS II—SPECIAL RISK.—A tobacco
 2 product or group of products that cannot be
 3 classified as a Class I tobacco product because
 4 it is—

5 “(i) of greater risk than a Class I
 6 product; or

7 “(ii) there is insufficient evidence to
 8 classify such product or group of products
 9 as Class I products;
 10 shall be referred to as a ‘Class II product’.

11 “(C) CLASS III—ENHANCED RISK.—A to-
 12 bacco product or group of products that—

13 “(i) is of greater risk than a Class II
 14 product;

15 “(ii) there is insufficient evidence to
 16 classify such product or group of products
 17 as Class II products; or

18 “(iii) presents a potentially unreason-
 19 able risk of illness or injury;
 20 shall be referred to as a ‘Class III product’.

21 “(2) DETERMINATIONS.—For purposes of this
 22 section, the classification of a tobacco product or
 23 group of products is to be determined considering—

24 “(A) the impact on youth tobacco use and
 25 health;

1 “(B) data supporting actual levels of risk,
2 exposure or harm due to the product; and

3 “(C) any implied reduction in levels of
4 risk, exposure or harm due to the product or its
5 labeling.

6 “(b) ESTABLISHMENT OF PANEL.—

7 “(1) IN GENERAL.—For the purpose of secur-
8 ing recommendations with respect to the classifica-
9 tion of tobacco products or groups of products, the
10 Secretary shall establish a panel of experts to be
11 known as the Tobacco Risk Classification Panel (re-
12 ferred to in this section as the ‘panel’).

13 “(2) MEMBERS.—The Secretary shall appoint
14 to the panel individuals who are qualified by training
15 and experience to evaluate the risk and relative risk
16 of tobacco products and who, to the extent feasible,
17 possess skill in the study of the health effects of to-
18 bacco products, or experience in tobacco cessation,
19 control and prevention. The Secretary shall des-
20 ignate one of the members of such panel to serve as
21 the chairperson.

22 “(3) ADMINISTRATIVE PROVISIONS.—

23 “(A) COMPENSATION AND EXPENSES.—
24 Members of the panel (other than officers or
25 employees of the United States), while attend-

1 ing meetings or conferences of the panel or oth-
2 erwise engaged in its business, shall be entitled
3 to receive compensation at rates to be fixed by
4 the Secretary, but not at rates exceeding the
5 daily equivalent of the rate in effect for grade
6 GS-18 of the General Schedule, for each day so
7 engaged, including travel time, and while so
8 serving away from their homes or regular places
9 of business each member may be allowed travel
10 expenses (including per diem in lieu of subsist-
11 ence) as authorized by section 5703 of title 5,
12 United States Code, for persons in the Govern-
13 ment service employed intermittently.

14 “(B) STAFF AND ASSISTANCE.—The Sec-
15 retary shall furnish the panel with adequate
16 clerical and other necessary assistance.

17 “(C) MEETINGS.—The panel shall meet at
18 such times as may be appropriate to enable the
19 Secretary to meet applicable statutory dead-
20 lines.

21 “(D) LIMITATIONS.—The panel shall not
22 be subject to the annual chartering and annual
23 report requirements of the Federal Advisory
24 Committee Act. Section 14 of such Act shall
25 not apply to the duration of the panel.

1 “(4) DUTIES.—The panel shall make rec-
2 ommendations to the Secretary concerning the clas-
3 sification of tobacco products.

4 “(c) CLASSIFICATION.—

5 “(1) IN GENERAL.—Not later than 15 months
6 after the date of enactment of this section, and as
7 necessary thereafter for new products, the Secretary,
8 based on the recommendations of the panel, shall
9 classify all tobacco products into the classes estab-
10 lished under subsection (a). Such classification may
11 be made for a group of similar or related products.

12 “(2) ACTIONS OF PANEL.—

13 “(A) IN GENERAL.—Upon the completion
14 of the panel’s review of a tobacco product or
15 group of products referred to it under para-
16 graph (1), the panel shall submit to the Sec-
17 retary its recommendation for the classification
18 of the tobacco product or group of products.

19 Any such recommendation shall contain—

20 “(i) a summary of the reasons for the
21 recommendation;

22 “(ii) a summary of the data upon
23 which the recommendation is based; and

24 “(iii) an identification of the risks to
25 health presented by the tobacco product or

1 group of products with respect to which
2 the recommendation is made.

3 “(B) REVIEW AND FINAL DETERMINATION
4 BY SECRETARY.—After receiving the conclu-
5 sions and recommendations of the panel on a
6 matter that the panel has reviewed under this
7 section, the Secretary shall review the conclu-
8 sions and recommendations, shall make a final
9 decision on the matter, and shall notify the af-
10 fected persons of the decision in writing and, if
11 the decision differs from the conclusions and
12 recommendations of the panel, shall include the
13 reasons for the difference.

14 “(C) SUBMISSION OF RECOMMENDA-
15 TIONS.—Not later than 1 year after the date of
16 enactment of this section, the panel shall sub-
17 mit to the Secretary recommendations con-
18 cerning all tobacco products or groups of prod-
19 ucts introduced or delivered for introduction
20 into interstate commerce for commercial dis-
21 tribution before the date of the enactment of
22 this section.

23 “(3) PUBLICATION.—Upon receipt of a rec-
24 ommendation from a panel under paragraph (2)(C),
25 the Secretary shall publish in the Federal Register

1 the panel's recommendation and a proposed regula-
 2 tion classifying such tobacco product or group of
 3 products under subsection (a).

4 “(4) EXISTING PRODUCTS.—In the case of a to-
 5 bacco product or group of products which has been
 6 introduced or delivered for introduction into inter-
 7 state commerce for commercial distribution before
 8 the date of enactment of this section, the panel shall
 9 recommend to the Secretary that the tobacco prod-
 10 uct or group of products be classified as a Class III
 11 product unless the panel determines that classifica-
 12 tion of the tobacco product or group of products in
 13 such class is not necessary. If a panel does not rec-
 14 ommend that such a tobacco product or group of
 15 products be classified as a Class III product, it shall
 16 in its recommendation to the Secretary for the clas-
 17 sification of the tobacco product or group of prod-
 18 ucts set forth the reasons for not recommending
 19 classification of the tobacco product in such class.

20 “(5) NEW PRODUCTS.—

21 “(A) IN GENERAL.—Any tobacco product
 22 or group of products which was not introduced
 23 or delivered for introduction into interstate
 24 commerce for commercial distribution before
 25 the date of the enactment of this section shall

1 be classified as a Class III product unless the
2 Secretary in response to a recommendation of
3 the panel has classified such tobacco product or
4 group of products as a Class I or Class II prod-
5 uct.

6 “(B) LIMITATION.—A tobacco product or
7 group of products classified as a Class III prod-
8 uct under this subsection shall be classified in
9 that class until the effective date of an order of
10 the Secretary classifying the tobacco product or
11 group of products as a Class I or Class II prod-
12 uct.

13 “(6) ACCESS TO DATA.—Any person whose to-
14 bacco product is specifically the subject of review by
15 the panel shall have—

16 “(A) the same access to data and informa-
17 tion submitted to the panel (except for data and
18 information that are not available for public
19 disclosure under section 552 of title 5, United
20 States Code) as the Secretary; and

21 “(B) the opportunity to submit, for review
22 by the panel, additional information, which
23 shall be submitted to the Secretary for prompt
24 transmittal to the panel.

1 “(7) MEETINGS.—Any meetings of the panel
2 shall provide adequate time for initial presentations
3 and for response to any differing views by persons
4 whose tobacco products are specifically the subject of
5 panel review, and shall encourage free and open par-
6 ticipation by all interested persons.

7 “(d) CLASSIFICATION CHANGES.—

8 “(1) IN GENERAL.—Based on new information
9 concerning a tobacco product or group of products,
10 the Secretary may by regulation change the classi-
11 fication of such tobacco product or group of prod-
12 ucts. In promulgating a regulation regarding a
13 change in the classification of a tobacco product or
14 group of products, the Secretary may secure from
15 the panel a recommendation concerning the proposed
16 change in the classification of the tobacco product or
17 group of products and shall publish in the Federal
18 Register any recommendation submitted to the Sec-
19 retary by the panel with respect to such change.

20 “(2) CLASS CHANGES.—By regulation promul-
21 gated under paragraph (1), the Secretary may
22 change the classification of a tobacco product from
23 Class III to Class II or Class I only if the appro-
24 priate relative risk determination has been made.”.

1 **SEC. 502. AUTHORITY TO PROHIBIT NICOTINE.**

2 Subchapter I of chapter VII of the Federal Food,
3 Drug, and Cosmetic Act (as amended by section 501) is
4 further amended by adding at the end the following:

5 **“SEC. 766. AUTHORITY TO PROHIBIT NICOTINE.**

6 “The Secretary may prohibit the introduction or de-
7 livery for introduction into interstate commerce of any
8 product that contains nicotine if such product has no
9 health benefit.”.

10 **SEC. 503. COUNTER-ADVERTISING.**

11 Part A of title V of the Public Health Service Act
12 (42 U.S.C. 290aa et seq.) is amended by adding at the
13 end the following:

14 **“SEC. 506C. TOBACCO USE COUNTER-ADVERTISING.**

15 “The Secretary, acting through the Administrator of
16 the Substance Abuse and Mental Health Services Admin-
17 istration, shall carry out a campaign of counter-adver-
18 tising with respect to tobacco use. The campaign shall con-
19 sist of the placement of pro-health advertisements regard-
20 ing tobacco use on television, on radio, in print, on bill-
21 boards, on movie trailers, on the Internet, and in other
22 media.”.

23 **SEC. 504. MEDICARE COVERAGE OF COUNSELING FOR CES-**
24 **SATION OF TOBACCO USE.**

25 (a) COVERAGE.—Section 1861(s)(2) of the Social Se-
26 curity Act (42 U.S.C. 1395x(s)(2)) is amended—

1 (1) in subparagraph (Z), by striking “and” at
2 the end;

3 (2) in subparagraph (AA), by inserting “and”
4 at the end; and

5 (3) by adding at the end the following new sub-
6 paragraph:

7 “(BB) counseling for cessation of tobacco use
8 (as defined in subsection (ccc));”.

9 (b) SERVICES DESCRIBED.—Section 1861 of the So-
10 cial Security Act (42 U.S.C. 1395x) is amended by adding
11 at the end the following new subsection:

12 “(ccc) COUNSELING FOR CESSATION OF TOBACCO
13 USE.—(1)(A) Subject to subparagraph (B), the term
14 ‘counseling for cessation of tobacco use’ means diagnostic,
15 therapy, and counseling services for cessation of tobacco
16 use for individuals who use tobacco products or who are
17 being treated for tobacco use which are furnished—

18 “(i) by or under the supervision of a physician;

19 “(ii) by a practitioner described in clause (i),
20 (iii), (iv), (v) or (vi) of section 1842(b)(18)(C); or

21 “(iii) by a licensed tobacco cessation counselor
22 (as defined in paragraph (2)).

23 “(B) Such term is limited to—

24 “(i) services recommended in ‘Treating Tobacco
25 Use and Dependence: A Clinical Practice Guideline’,

1 published by the Public Health Service in June
 2 2000, or any subsequent modification of such Guide-
 3 line; and

4 “(ii) such other services that the Secretary rec-
 5 ognizes to be effective.

6 “(2) In this subsection, the term ‘licensed tobacco
 7 cessation counselor’ means a tobacco cessation counselor
 8 who—

9 “(A) is licensed as such by the State (or in a
 10 State which does not license tobacco cessation coun-
 11 selors as such, is legally authorized to perform the
 12 services of a tobacco cessation counselor in the juris-
 13 diction in which the counselor performs such serv-
 14 ices); and

15 “(B) meets uniform minimum standards relat-
 16 ing to basic knowledge, qualification training, con-
 17 tinuing education, and documentation that are es-
 18 tablished by the Secretary for purposes of this sub-
 19 section.”.

20 (c) PAYMENT AND ELIMINATION OF COST-SHARING
 21 FOR COUNSELING FOR CESSATION OF TOBACCO USE.—

22 (1) PAYMENT AND ELIMINATION OF COINSUR-
 23 ANCE.—Section 1833(a)(1) of the Social Security
 24 Act (42 U.S.C. 1395l(a)(1)) is amended—

25 (A) by striking “and” before “(V)”; and

(B) by inserting before the semicolon at the end the following: “, and (W) with respect to counseling for cessation of tobacco use (as defined in section 1861(ccc)), the amount paid shall be 100 percent of the lesser of the actual charge for the service or the amount determined by a fee schedule established by the Secretary for purposes of this subparagraph”.

(2) ELIMINATION OF COINSURANCE IN OUT-PATIENT HOSPITAL SETTINGS.—

(A) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by striking “and diagnostic mammography” and inserting “, diagnostic mammography, or counseling for cessation of tobacco use (as defined in section 1861(ccc))”.

(B) CONFORMING AMENDMENTS.—Section 1833(a)(2) of the Social Security Act (42 U.S.C. 1395l(a)(2)) is amended—

- (i) in subparagraph (F), by striking “and” after the semicolon at the end;
- (ii) in subparagraph (G)(ii), by striking the comma at the end and inserting “; and”;

1 (iii) by inserting after subparagraph
 2 (G)(ii) the following new subparagraph:

3 “(H) with respect to counseling for ces-
 4 sation of tobacco use (as defined in section
 5 1861(ccc)) furnished by an outpatient depart-
 6 ment of a hospital, the amount determined
 7 under paragraph (1)(W),”.

8 (3) ELIMINATION OF DEDUCTIBLE.—The first
 9 sentence of section 1833(b) of the Social Security
 10 Act (42 U.S.C. 1395l(b)) is amended—

11 (A) by striking “and” before “(8)”; and

12 (B) by inserting before the period the fol-
 13 lowing: “, and (9) such deductible shall not
 14 apply with respect to counseling for cessation of
 15 tobacco use (as defined in section 1861(ccc))”.

16 (d) APPLICATION OF LIMITS ON BILLING.—Section
 17 1842(b)(18)(C) of the Social Security Act (42 U.S.C.
 18 1395u(b)(18)(C)) is amended by adding at the end the
 19 following new clause:

20 “(vii) A licensed tobacco cessation counselor (as
 21 defined in section 1861(ccc)(2)).”.

22 (e) INCLUSION AS PART OF INITIAL PREVENTIVE
 23 PHYSICAL EXAMINATION.—Section 1861(ww)(2) of the
 24 Social Security Act (42 U.S.C. 1395x(ww)(2)) is amended
 25 by adding at the end the following new subparagraph:

1 “(M) Counseling for cessation of tobacco use
2 (as defined in subsection (ccc)).”.

3 (f) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to services furnished on or after
5 the date that is 1 year after the date of enactment of this
6 Act.

7 **SEC. 505. MEDICARE COVERAGE OF TOBACCO CESSATION**
8 **PHARMACOTHERAPY.**

9 Section 1860D–2(e)(1) of the Social Security Act (42
10 U.S.C. 1395w–102(e)(1)) is amended—

11 (1) in subparagraph (A), by striking “or” after
12 the semicolon at the end;

13 (2) in subparagraph (B), by striking the comma
14 at the end and inserting “; or”; and

15 (3) by inserting after subparagraph (B) the fol-
16 lowing new subparagraph:

17 “(C) any agent approved by the Food and
18 Drug Administration for purposes of promoting,
19 and when used to promote, tobacco cessation
20 that may be dispensed without a prescription
21 (commonly referred to as an ‘over-the-counter’
22 drug), but only if such an agent is prescribed
23 by a physician (or other person authorized to
24 prescribe under State law),”.

1 **SEC. 506. TOBACCO CESSATION FOR FEDERAL EMPLOYEE**
2 **HEALTH BENEFITS PLANS.**

3 (a) CONTRACT REQUIREMENT.—Section 8902 of title
4 5, United States Code, is amended by adding at the end
5 the following:

6 “(p) Each contract under this chapter shall require
7 the carrier to provide for the establishment and mainte-
8 nance of a tobacco cessation program.”.

9 (b) EFFECTIVE DATE AND APPLICATION.—The
10 amendment made by this section shall take effect on the
11 date of enactment of this Act and apply with respect to
12 contracts for health benefits plans under chapter 89 of
13 title 5, United States Code, which take effect on and after
14 January of the first calendar year following 1 year after
15 the date of enactment of this Act.

16 **SEC. 507. MATCHING GRANTS FOR STATES THAT USE A SIG-**
17 **NIFICANT PORTION OF MASTER SETTLEMENT**
18 **AGREEMENT FUNDS FOR TOBACCO CONTROL**
19 **AND CESSATION.**

20 Title XXX of the Public Health Service Act, as added
21 by section 301, is amended by adding at the end the fol-
22 lowing:

1 **“SEC. 3009. MATCHING GRANTS FOR STATES THAT USE A**
 2 **SIGNIFICANT PORTION OF MASTER SETTLE-**
 3 **MENT AGREEMENT FUNDS FOR TOBACCO**
 4 **CONTROL AND CESSATION.**

5 “(a) IN GENERAL.—The Secretary may award
 6 matching grants to eligible States to enable such States
 7 to carry out additional tobacco control and cessation ac-
 8 tivities.

9 “(b) ELIGIBILITY.—To be eligible to receive a grant
 10 under subsection (a), a State shall—

11 “(1) demonstrate to the satisfaction of the Sec-
 12 retary that, with respect to the calendar year pre-
 13 ceding the year in which the State is applying for
 14 such a grant, the State expended in excess of 25
 15 percent of the funds paid to the State for such year
 16 as part of the comprehensive settlement of Novem-
 17 ber 1998 referred to in section 1903(d)(3)(B)(i) of
 18 the Social Security Act on tobacco control and ces-
 19 sation activities; and

20 “(2) submit to the Secretary an application at
 21 such time, in such manner, and containing such in-
 22 formation as the Secretary may require.

23 “(c) AMOUNT OF GRANT.—With respect to a grant
 24 under this section, an eligible State may receive not to
 25 exceed an amount equal to 50 percent of the amount ex-

1 pended by the State in excess of the 25 percent of funds
2 described in subsection (b)(1) for the year involved.

3 “(d) FUNDING.—The Secretary shall use amounts
4 made available in each fiscal year under section 401(g)(3)
5 of the Help End Addiction to Lethal Tobacco Habits Act
6 to carry out this section.”.

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